K063020 page 1 of 3

510(k) Summary of Safety and Effectiveness

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92.

DEC 14 2006

Company : INTAI Technology Corp.

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Taichung City, 407, Taiwan, R.O.C.

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Contact Person : Simon Tsai

Orthopedic Division Vice General Manager

Registration Number :

Prepared Date : September 8, 2006

Proprietary Name : INTAI Bone Plate and Bone Screw System & INTAI DHS/DCS Plate System

Common Name : Bone Plate and Bone Screw System

Reviewing Panel : Orthopedic

Classification Name :

- Class II : Plate, Fixation, Bone
  HRS – CFR 888.3030
- Class II : Screw, Fixation, Bone
  HWC – CFR 888.3040
- Class II : Appliance, fixation, nail/blade/plate combination, multiple component
  KTT – CFR 888.3030

Predicate devices :

SYNTEC-TAICHUNG NON-STERILE BONE PLATE AND SCREW (K983495)

SYNTEC-TAICHUNG NON-STERILE DHS/DCS PLATE SYSTEM (K983873)

page 4-2

Material :

The devices are manufactured from medical grade 316L stainless steel that meet ASTM 138&ASTM 139/ISO 5832-1 and Titanium Alloy (Ti-6AL-4V) that meet ASTM 136/ISO 5832-3.

Indication for Use :

The Bone Plate and Bone Screw System and the DHS/DCS Plate System are provided non-sterile.

The Bone Plate and Bone Screw System is intended for use in fixation of fractures to the various bones, including the clavicle, pelvis, scapula, calcaneus, long bone (humerus, ulna, radius, femur, tibia, and fibula), and small bone (metacarpals, metatarsals, and phalanges).

The DHS/DCS Plate System is intended for use in fixation of fractures to the proximal femur. The system is indicated for use in trochanteric, pertrochanteric, intertrochanteric, and basilar neck fractures.

Description of the Device :

The Bone Plate and Bone Screw System & the DHS/DCS Plate System consist of non-sterile bone plate and bone screw implants. The plates are devices, which are fastened to bone for purpose of providing fixation. The plates are provided in various types according to different function. Thus there are four kind of styles : Dynamic Compression Plate (DCP), tubular, special and DHS/DCS. The shape of the plate is an adaptation of the plate to the local anatomy and doesn't denote any function. Thus the name depends on the biomechanical function the plate is performing. The plates are divided various types as following :

Plate Name	Geometry Shape
DCP	narrow, broad, lengthening-narrow, lengthening-broad, straight
Tubular	semi-tubular, one-third, quarter
Special	T-shaped, T-buttress, T-oblique, L-shaped, L-buttress, cobra head, lateral tibial head, condylar, condylar buttress, spoon, reconstruction, reconstruction-curved, hook, H-shaped, W-shaped cloverleaf, calcaneal, Y-Calcaneal, Adaptation
DHS/DCS	Dynamic Hip Screw, Dynamic Condylar Screw

The series in size of bone screw and bone plate except DHS/DCS are divided into mini, small and large. The size range of plates are in thickness from 1.0 to 6.0mm, width from 3.8 to 17mm, length from 17 to 359mm, and hole number from 2 to 22 holes.

On the other hand, the screws used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for. Thus there are four kind of style : cortex, cancellous, malleolar and cannulated screws. All screws have a hexagonal recess; this feature has proven itself to be of grate advantage at the time of the screw removal and insertion. The size range of screws is in thread diameter from 1.5 to 7.3 mm, total length from 6 to 150mm.

The DHS/DCS Plate System consists of DHS/DCS Plate, DHS/DCS Screw, DHS/DCS Compression Screw, and 4.5mm Cortex Screw (self-tapping). The DHS Plates are available with short and standard barrel which length is 25mm and 38mm respectively. And the barrel angles are available in 95°, 135°, 140°, 145° and 150°. The self-tapping 4.5mm Cortex Screw can be used to fix the DHS/DCS Plate to the femoral shaft.

The DHS/DCS Screw is available in total length from 50 to 145 mm, thread length 22mm, shaft diameter 7.9mm, and outer diameter from 12.5 to 14mm. The thread of DHS/DCS Screw has a buttress type.

The DHS/DCS Compression Screw can be used to achieve fracture compression. Its dimension is available with thread length 26mm and outer diameter 4.0 mm.

Substantial Equivalence :

The INTAI Bone Plate and Bone Screw System & INTAI DHS/DCS Plate System is substantially equivalent to SYNTEC-TAICHUNG NON-STERILE BONE PLATE AND SCREW (K983495) and SYNTEC-TAICHUNG NON-STERILE DHS/DCS PLATE SYSTEM (K983873).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2006

INTAI Technology Corp.
% Aoltec International, Inc.
Peiwen Lin
4230 East Airport Drive, Suite 110
Ontario, California 91761

Re: K063020
Trade/Device Name: INTAI Bone Plate and Bone Screw System & INTAI DHS/DCS Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, KTT, HWC
Dated: September 8, 2006
Received: October 2, 2006

Dear Peiwen Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

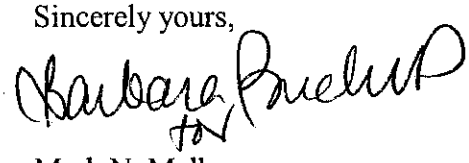
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 4. Proposed Labeling

4.1 Indications for Use

Indications for Use

510(k) Number (if known): K063020

Device Name: **INTAI Bone Plate and Bone Screw System & INTAI DHS/DCS Plate System**

Indications for Use:

The Bone Plate and Bone Screw System and the DHS/DCS Plate System are provided non-sterile.

The Bone Plate and Bone Screw System is intended for use in fixation of fractures to the various bones, including the clavicle, pelvis, scapula, calcaneus, long bone (humerus, ulna, radius, femur, tibia, and fibula), and small bone (metacarpals, metatarsals, and phalanges).

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K063020